UNITED STATES DISTRICT COURT

for the Eastern District of New York

District of Eastern New York

Division Civil

Case No. CV18 2788
(to be filled in by the Clerk's Office)

SEYBERT, J.

SHIELDS, M.J.

Jay Brodsky

Plaintiff(s)
(Write the full name of each plaintiff who is filing this complaint. If the names of all the plaintiffs cannot fit in the space above, please write "see attached" in the space and attach an additional page with the full list of names.)

-v-

Purdue Pharma et al

Defendant(s)
(Write the full name of each defendant who is being sued. If the names of all the defendants cannot fit in the space above, please write "see attached" in the space and attach an additional page with the full list of names.)

Jury Trial: *(check one)* Yes

COMPLAINT FOR A CIVIL CASE

I. The Parties to This Complaint

A. The Plaintiff(s)

Provide the information below for each plaintiff named in the complaint. Attach additional pages if needed.

Name	Jay Brodsky
Street Address	240 East Shore Road #444
City and County	Great Neck Nassau County
State and Zip Code	New York 11023
Telephone Number	973-568-1666

E-mail Address demcointerexport@yahoo.com

B. The Defendant(s)

Provide the information below for each defendant named in the complaint, whether the defendant is an individual, a government agency, an organization, or a corporation. For an individual defendant, include the person's job or title *(if known)*. Attach additional pages if needed.

Defendant No. 1

Name Purdue Pharma L.P.

Job or Title *(if known)*

Street Address One Stamford Forum, 201 Tresser Blvd.

City and County Stamford

State and Zip Code CT. 06901-3431

Telephone Number

E-mail Address *(if known)*

Defendant No. 2

Name See Attached Addendum

Job or Title *(if known)*

Street Address

City and County

State and Zip Code

Telephone Number

E-mail Address *(if known)*

Defendant No. 3

Name

Job or Title *(if known)*

Street Address

City and County

State and Zip Code

Telephone Number

E-mail Address *(if known)*

Defendant No. 4

Name

Job or Title *(if known)*

Street Address

City and County

State and Zip Code

Telephone Number

E-mail Address *(if known)*

II. Basis for Jurisdiction

Federal courts are courts of limited jurisdiction (limited power). Generally, only two types of cases can be heard in federal court: cases involving a federal question and cases involving diversity of citizenship of the parties. Under 28 U.S.C. § 1331, a case arising under the United States Constitution or federal laws or treaties is a federal question case. Under 28 U.S.C. § 1332, a case in which a citizen of one State sues a citizen of another State or nation and the amount at stake is more than $75,000 is a diversity of citizenship case. In a diversity of citizenship case, no defendant may be a citizen of the same State as any plaintiff.

What is the basis for federal court jurisdiction? *(check all that apply)*

Federal question xxx Diversity of citizenship xxx

Fill out the paragraphs in this section that apply to this case.

A. If the Basis for Jurisdiction Is a Federal Question

List the specific federal statutes, federal treaties, and/or provisions of the United States Constitution that are at issue in this case.

15 U.S.C.A. 1125
21 U.S.C.A. 352, 355,
262 of Title 42
21 U.S.C.A. 331
28 U.S.C.A. 1331

B. If the Basis for Jurisdiction Is Diversity of Citizenship

1. The Plaintiff(s)

a. If the plaintiff is an individual

The plaintiff, *(name)* Jay Brodsky , is a citizen of the State of *(name)* New York .

b. If the plaintiff is a corporation

The plaintiff, *(name)* , is incorporated under the laws of the State of *(name)* , and has its principal place of business in the State of *(name)* .

(If more than one plaintiff is named in the complaint, attach an additional page providing the same information for each additional plaintiff.)

2. The Defendant(s)

a. If the defendant is an individual

The defendant, *(name)* , is a citizen of the State of *(name)* . Or is a citizen of *(foreign nation)* .

b. If the defendant is a corporation

The defendant, *(name)* Purdue Pharma , is incorporated under the laws of the State of *(name)* Deleware , and has its principal place of business in the State of *(name)* Connecticut . Or is incorporated under the laws of *(foreign nation)* , and has its principal place of business in *(name)* .

(If more than one defendant is named in the complaint, attach an additional page providing the same information for each additional defendant.)

3. The Amount in Controversy

The amount in controversy–the amount the plaintiff claims the defendant owes or the amount at stake–is more than $75,000, not counting interest and costs of court, because *(explain)*:

$3,000,000.00 plus other at the courts discretion

III. Statement of Claim

Write a short and plain statement of the claim. Do not make legal arguments. State as briefly as possible the facts showing that each plaintiff is entitled to the damages or other relief sought. State how each defendant was involved and what each defendant did that caused the plaintiff harm or violated the plaintiff's rights, including the dates and places of that involvement or conduct. If more than one claim is asserted, number each claim and write a short and plain statement of each claim in a separate paragraph. Attach additional pages if needed.

See Attached addendum

IV. Relief

State briefly and precisely what damages or other relief the plaintiff asks the court to order. Do not make legal arguments. Include any basis for claiming that the wrongs alleged are continuing at the present time. Include the amounts of any actual damages claimed for the acts alleged and the basis for these amounts. Include any punitive or exemplary damages claimed, the amounts, and the reasons you claim you are entitled to actual or punitive money damages.

See attached addendum

V. Certification and Closing

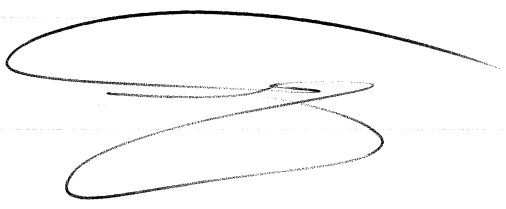
Under Federal Rule of Civil Procedure 11, by signing below, I certify to the best of my knowledge, information, and belief that this complaint: (1) is not being presented for an improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation; (2) is supported by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law; (3) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery; and (4) the complaint otherwise complies with the requirements of Rule 11.

A. For Parties Without an Attorney

I agree to provide the Clerk's Office with any changes to my address where case-related papers may be served. I understand that my failure to keep a current address on file with the Clerk's Office may result in the dismissal of my case.

Date of signing: May 5, 2018

Signature of Plaintiff



Printed Name of Plaintiff Jay Brodsky

B. For Attorneys

Date of signing:

Signature of Attorney

Printed Name of Attorney

Bar Number

Name of Law Firm

Street Address

State and Zip Code

Telephone Number

E-mail Address

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

THE MATTER OF:

JAY BRODSKY	PETITIONER
-against-	
PURDUE PHARMA L.P. PURDUE PHARMA INC. THE PURDUE FREDERICK COMPANY INC. TEVA PHARMACEUTICALS INC. CEPHALON, INC. JOHNSON & JOHNSON JANSSEN PHARMACEUTICALS, INC N/K/A JANSSEN PHARMACEUTICALS, INC.; DEPOMED, INC. ORTHO-McNEIL ENDO HEALTH SOLUTIONS INC.; ENDO PHARACEUTICALS, INC.; ALLERGEN PLC; F/K/A ACTAVIS PLC.; ACTAVIS, INC. F/K/A WATSON LABORATORIES, INC.; ACTAVIS LLC; and ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC.,	RESPONDENTS Case no._____

COMPLAINT

AFFIRMATION:

1. On this 30th day of April, 2018, Pursuant to Federal Rules of Civil Procedure Rule 7(a), the Petitioner, Jay Brodsky aka known as, Mr. Brodsky, resides at, 240 East Shore Road, Apartment 444, Great Neck, New York 11023, duly deposes that the facts as stated herein are true to the best of his knowledge. Petitioner initiates this adjudication pursuant to Rule (8) of the Federal Rules of Civil Procedure.

VENUE AND JURISTICTION:

2. Venue is appropriate under 28 U.S.C.A. § 1332 because, among other things: the plaintiff, Jay Brodsky resides and is a citizen of New York State, County of Nassau; The respondents conduct business and directs their activities to residents of New York State, County of Nassau.

2(b) The United States District Court for the Eastern District of New York has jurisdiction over the parties because the respondents conduct a major part of their national operations and conduct business activities from their headquarters in various other states outside the purview of New York State, with an advertising budget not exceeded in other jurisdictions throughout the United States.

3. The court also has jurisdiction under 28 U.S.C.A. § 1331 as the respondents et al violated, 21 U.S.C.A. § 352, Misbranded Drugs and Devices, which states;

"If it's labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement, shall not be considered to be false or misleading under this paragraph if the health care economic information relates to an indication approved under section 355 of this title or under section 262(a) of Title 42 for such drug, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 355 of this title or under section 262 of Title 42. The requirements set forth in section 355(a) of this title or in subsections (a) and (k) of section 262 of Title 42 shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request."

THE PARTIES:

4. Pursuant to the Federal Rules of civil Procedure, Rule 7(a), the parties to this action are as follows:

5. PETITIONER,

Jay Brodsky, 240 East Shore Road #444, Great Neck, New York, 11023.

6. THE RESPONDENTS,

1. Purdue Pharma L.P., One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431
2. Purdue Pharma Inc., One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431
3. Purdue Frederick Company Inc., One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431
4. TEVA Pharmaceuticals Inc., 1090 Horsham Road, North Wales, Pa. 19454
5. Cephalon Inc., 41 Moores Road, Frazer, PA 19355
6. Johnson & Johnson, 1 Johnson And Johnson Plz, New Brunswick NJ 08933
7. Janssen Pharmaceuticals Inc. N/K/A, 1000 U.S. Route 202 S. Raritan, NJ 08869

8. Janssen Pharmaceuticals Inc., 1000 U.S. Route 202 South, Raritan, NJ 08869

10. DEPOMED Inc., 7999 Gateway Blvd., Suite 300, Newark, CA 94560

11. Ortho-McNeill, 1000 U.S. Route 202, South Raritan, NJ 08869

12. Endo Health Solutions Inc., 1400 Atwater Drive, Malvern, PA 19355

13. Endo Pharmaceuticals Inc., 1400 Atwater Drive, Malvern, PA 19355

14. Allergen PLC; F/K/A Actavis PLC.; 5 Giralda Farms, Madison, NJ 07940

15. Actavis, INC. F/K/A, 400 Interpace Parkway # A1, Parsippany, NJ 07054

16. Watson Laboratories Inc., 132 Business Center Drive, Corona, CA 92880-1724

17. Actavis LLC; and Actavis Pharma, Inc., 400 Interpace Parkway # A1, Parsippany, NJ 07054

18. F/K/A Watson Pharma, Inc., 132 Business Center Drive, Corona, CA 92880

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JURY DEMAND

9. Jay Brodsky demands a jury trial in conjunction with the Seventh Amendment to the Constitution pursuant to Federal Rule of Civil Procedure 38.

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FIRST FACTS OF SUBSTANTIAL IMPORTANCE:

Petitioners Background

10. The Petitioner, Jay Brodsky is a Sixty-Four year old male. He was first diagnosed with Rheumatoid and Psoriatic Arthritis on or around 1981. Throughout the many years since he was first diagnosed, there has been severe deforming of his bone structure in congruence with a disease that is highly aggressive and destructive. As a result of Petitioners many years of suffering the asperities of this disease, he has suffered greatly.

11. From the inception of being afflicted with Arthritis, there were few options available for treatment. Mainly there was great need to address the pain which was overwhelming and destructive.

12. As early as 1995, when the petitioner resided in Chevy Chase, Maryland he was being treated by a rheumatologist, Dr. Michell Fineman, in Washington D.C. After an extensive examination, he determined that such an aggressive form of Rheumatoid Arthritis had only a few options for treatment available. One treatment was systemic intervention by injecting Cortisone [Kenalog] intramuscularly, however a patient shouldn't get cortisone injections more often than every six weeks and usually not more than three or four times a year.

13. The second course of action to curtail the pain was to orally ingest doses of Oxycodone, Tylenol with codeine or Percocet. All highly addictive drugs that were never intended for the long term treatment of pain. However the doctor assured the petitioner that treatment with these schedule II narcotics were a safe and effective way to abate suffering from chronic pain.

14. Oxycodone is a semisynthetic opioid synthesized from thebaine, an opioid alkaloid found in the Persian poppy, and one of the many alkaloids found in the opium poppy. It is a moderately potent opioid pain medication (orally roughly 1.5 times more potent than morphine), generally indicated for relief of moderate to severe pain. Oxycodone was developed in 1917 in Germany as one of several semi-synthetic opioids in an attempt to improve on the existing opioids.

15. In 1996 the petitioner returned to New York and became a patient of Dr. Jason Faller, who to this day is the petitioners treating Rheumatologist.

16. Dr. Faller suggested the petitioner begin taking a regiment of a new drug called, Oxycontin. Touted as the wonder drug for treating pain, the manufacturer, Purdue Pharma, claimed that Oxycontin was effective for twelve hours with little to know chance for addiction.

17. OXYCONTIN is:

• A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them.

• A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

• Not for use to treat pain that is not around-the-clock.

• Not for use in children less than 11 years of age and who are not already using opioid pain medicines regularly to manage pain

severe enough to require daily around-the-clock long-term treatment of pain with an opioid .

18. The petitioner was prescribed Oxycontin and at first the drug was quite effective for treating pain. However, it didn't take long before the petitioner discovered that over time the drug was becoming less and less effective. At first the effects of the drug diminished enough so that the petitioner had to increase his dosage to every six hours.

19. Over a period of months the petitioner discovered that his doses of Oxycontin were only effective for five hours. In order to alleviate those periods of time between doses of Oxycontin, the petitioner was forced to supplement the efficacy of his treatment with Tylenol with codeine [Tylenol 3].

20. Over the next nine years the doses of Oxycontin, Oxycodone and Tylenol with codeine increased as the efficacy of these drugs decreased over time.

21. In 2005 a new wonder pain medication became available and was approved for the treatment of chronic pain. Fentanyl transdermal patches (Durogesic/Duragesic) are used in chronic pain management. The patches work by slowly releasing fentanyl through the skin into the bloodstream over 48 to 72 hours, allowing for long-lasting pain management. Dosage is based on the size of the patch, since, in general, the transdermal absorption rate is constant at a constant skin temperature. Rate of absorption is dependent on a number of factors. Body temperature, skin type, amount of body fat, and placement of the patch can have major effects. The different delivery systems used by different makers will also affect individual rates of absorption. Under normal circumstances, the patch will reach its full effect within 12 to 24 hours; thus, fentanyl patches are often prescribed with a fast-acting opioid (such as morphine or oxycodone) to handle breakthrough pain.

22. Fentanyl, also spelled Fentanil, is an opioid which is used as a pain medication and together with other medications for anesthesia. It has a rapid onset and effects generally last less than an hour or two. Fentanyl is available in a number of forms including by injection, as a skin patch, and to be absorbed through the tissues inside the mouth.

Common side effects include nausea, constipation, sleepiness, and confusion.[2] Serious side effects may include a decreased effort to breathe (respiratory depression), serotonin syndrome, low blood pressure, or addiction. Fentanyl works in part by activating μ-opioid receptors. It is about 75 times stronger than morphine for a given amount. Some fentanyl analogues may be as much as 10,000 times stronger than morphine.

Fentanyl was first made by Paul Janssen in 1960 and approved for medical use in the United States in 1968. It was developed by testing chemicals similar in structure to pethidine (meperidine) for opioid activity. In 2015, 1,600 kilograms (3,500 lb) were used globally. As of 2017, fentanyl was the most widely used synthetic opioid in medicine.

Fentanyl patches are on the World Health Organization's List of Essential Medicines, the most effective and safe medicines needed in a health system.[10] The

wholesale cost in the developing world as of 2015 is between US$0.08 and US$0.81 per 100 microgram vial. In the United States this amount costs about US$0.40 as of 2017. Fentanyl is also made illegally and used as a recreational drug often mixed with heroin or cocaine. In 2016 more than 20,000 deaths occurred in the United States due to overdoses of fentanyl and its analogues.

23. The petitioner in this action has been prescribed opioid medications for Twenty-Three years. These highly addictive drug's have effected his life negatively in many ways which will be presented to the court during trial. It is now nearly impossible to for the petitioner to live without taking opioids on a daily basis. As it turned out, these insidious drugs rule his life.

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SECOND FACTS OF SUBSTANTIAL IMPORTANCE:

Opioid Drugs Defined

24. OxyContin is Purdue's largest-selling opioid, in both New York State and the nation. From 2009 to 2016, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

25. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million—at the time, one of the largest settlements with a drug company for marketing misconduct. Pursuant to its settlement, Purdue operated under a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services, which required the company, inter alia, to ensure that it's marketing was fair and accurate, and to monitor and report on its compliance with the Agreement.

26. The labels for OxyContin and other long-acting opioids were amended in response to a 2012 citizens' petition by doctors. The changes were intended to clarify the existing obligation to "make an individualized assessment of patient needs." The petitioners also successfully urged that the revised labels heighten the requirements for boxed label warnings related to addiction, abuse, and misuse by changing "Monitor for signs of misuse, abuse, and addiction" to "[Drug name] exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death." Letter from Bob Rappaport, Dir. Ctr. for Drug Evaluations & Res., Labeling Supplement and PMR [Post-Marketing Research] Required (Sept. 10, 2013), http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf.) to management of pain severe enough to require daily, around-

the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

27. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil- Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica Inc. Defendant ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Johnson & Johnson is the only company that owns more than 10% of Janssen Pharmaceuticals, Inc.'s stock, and it corresponds with the FDA regarding Janssen's products. Upon information and belief, Johnson & Johnson controls the sale and development of Janssen Pharmaceutical's drugs, and Janssen Pharmaceuticals, Inc.'s profits inure to Johnson & Johnson's benefit.

(Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and Johnson & Johnson collectively are referred to herein as "Janssen.")

28. Janssen manufactures, sells, and distributes a range of medical devices and pharmaceutical drugs in New York State and the rest of the nation, including Duragesic (fentanyl), which is a Schedule II opioid agonist transdermal patch first approved in 1990 and indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

29. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. (Teva Ltd."), an Israeli corporation. Teva USA is a Delaware corporation with its principal place of business in Pennsylvania.

30. Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva USA conducts Teva Ltd.'s sales and marketing activities for Cephalon in the United States and has done so since Teva Ltd.'s October 2011 acquisition of Cephalon. Teva USA holds out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon

branded products through its "specialty medicines" division. The FDA approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in New York State, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. (Teva USA and Cephalon, Inc. collectively are referred to herein as "Cephalon.")

31. Cephalon has been in the business of manufacturing, selling, and distributing the following opioids, nationally and in New York State:

32. Actiq (fentanyl citrate) is a Schedule II opioid agonist lozenge (lollipop) first approved in 1998 and indicated for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."

33. Fentora (fentanyl citrate) is a Schedule II opioid agonist buccal tablet (similar to plugs of smokeless tobacco) first approved in 2006 and indicated for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."

34. In November 1998, the FDA granted restricted marketing approval for Actiq, limiting its lawful promotion to cancer patients experiencing pain. The FDA specified that Actiq should not be marketed for off-label uses, stating that the drug must be prescribed solely to cancer patients. In 2008, Cephalon pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million in fines, damages, and penalties.

35. DEPOMED, INC. ("Depomed") is a California corporation with its principal place of business in Newark, California. Depomed describes itself as a specialty pharmaceutical company focused on pain and other central nervous system (CNS) conditions. Depomed develops, markets, and sells prescription drugs in New York State and nationally. Depomed acquired the rights to Nucynta and Nucynta ER for $1.05 billion from Janssen pursuant to a January 15, 2015 Asset Purchase Agreement. This agreement closed on April 2, 2015.

36. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS, INC. is a wholly- owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in

Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc. collectively are referred to herein as "Endo.")

37. Endo develops, markets, and sells prescription drugs, including the following opioids, in New York and nationally:

38. Opana ER (oxymorphone hydrochloride extended release) is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Opana ER was indicated for the "relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time."

39. Opana (oxymorphone hydrochloride) is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the "relief of moderate to severe acute pain where the use of an opioid is appropriate."

40. Percodan (oxycodone hydrochloride and aspirin) is a Schedule II opioid agonist tablet first approved in 1950 and first marketed by Endo in 2004 and indicated for the "management of moderate to moderately severe pain."

41. Percocet (oxycodone hydrochloride and acetaminophen) is a Schedule II opioid agonist tablet first approved in 1999 and appropriate injunctive relief as to Nucynta and Nucynta ER.

42. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and it alone accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, nationally and in New York State, both itself and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

43. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC in March 2015. Prior to that, WATSON PHARMACEUTICALS, INC. acquired Actavis, Inc. in October 2012; the combined company changed its name to Actavis, Inc. as of January 2013 and then to Actavis plc in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson

Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants are owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products.(Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter collectively are referred to as "Actavis.")

44. Actavis engages in the business of marketing and selling opioids in New York State and across the country, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. Kadian (morphine sulfate extended release) is a Schedule II opioid agonist capsule first approved in 1996 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Kadian was

indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time." Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

45. Teva USA is also in the business of selling generic opioids, nationally and in New York State, including a generic form of OxyContin from 2005 through 2009.

46. On September 29, 2008, Cephalon entered into a five-year Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The agreement, inter alia, required Cephalon to send doctors a letter advising them of the settlement terms and giving them a means to report questionable conduct of its sales representatives; disclose payments to doctors on its web site; and regularly certify that the company has an effective compliance program.

FACTUAL ALLEGATIONS

47. Medical practice relies on informed risk management. It is well known that the assessment of potential risks and benefits for each potential treatment is the basis in which drugs are prescribed, as well as assessing the risk of not treating underlying problems associated with pain. Therefore, the safe and effective treatment of

chronic pain requires that a physician be able to weigh the relative risks of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment and (b) the risks and benefits of alternatives.

48. The bedrock principle of full disclosure is of particular importance in deciding the efficacy of chronic opioid drug therapy because the risk to patients pertaining to eventually becoming physically and psychologically dependent will inevitably become nearly impossible to manage on their own or to eventually terminate their use.

49. Although the FDA, approved drug labels be affixed on each of Defendants' opioid prescriptions, they do not advise physicians about how to maximize the benefit and minimize risk for patients on their long-term use? The warning labels do not specify a dosage amount that might be potentially unsafe for a doctor to prescribe to their patients at any given time. These same warning labels do not provide a specified duration limit identifying the risks that a patient might encounter upon an increase in dosage. Therefore doctors and their patients can only rely on educational materials, such as treatment guidelines, [1] CMEs, scientific and patient education articles and websites, to educate them about their treatment decisions.

50. Opium and its pain-relieving properties have been recognized for centuries. There has also been a magnitude of information regarding its potential for abuse, addiction and overuse. Opioids are widely known to be closely related to illicit drugs like heroin. As early as the Civil War, opioids were widely referred to as "tinctures of laudanum," and as such increased in popularity among doctors and pharmacists as a prescription to alleviate anxiety and pain. This application particularly applied on the battlefield and as such were used widely in a variety of marketable products ranging from pain elixirs to cough medicine and even in some beverages. At the turn of the twentieth century nearly 300,000 people had become addicted to a variety of opioids throughout the United States as to many doctors prescribed these various opioid products exclusively to avoid patients' withdrawal. Taking this number of opioid addicts into consideration and the extraordinary difficulty these addicts had weaning themselves from opioid use made it as clear as day that they were highly addictive.

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Footnote [1]; **Continuing medical education** consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession.

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51. Stemming the tide of opioid addiction has long been thought to be paramount by both New York State and federal government. New York State and the federal government jointly announced on several occasions that "drug addiction [is] among the most serious health problems facing the people of the nation and the State of New York." The result, of these joint announcements led New York and the federal government to declare that their public policy was to promote and encourage . . . [the] successful treatment of . . . drug addiction." According to the New York Times, the Senate leadership initiated efforts to salvage the Republican health care bill that focused in part on adding $45 billion for states to spend on opioid addiction treatment.

52. Due to the known addictive properties of opioids, they have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings that specifically exemplify their potential addictive and potentially, life-threatening properties from fatal respiratory depression as a result of excessive dosing.

53. As Mr. Brodsky, the petitioner can well attest to, most individuals who are prescribed opioids will experience withdrawal symptoms within a few weeks if the opioids are discontinued. This withdrawal is widely referred to as being "dependent". Once dependent, it is common for a patient to experience painfully unpleasant symptoms after his or her present dosage of opioids starts to lose their effectiveness and is not immediately upgraded to a new higher dose. These withdrawal symptoms include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms and they will likely persist for months even after accomplishing a complete withdrawal from opioids. These contemptuous withdrawal symptoms continue in accordance with how long the opioids were administered.

54. Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a nationally recognized addiction treatment program, compared the effects of opioids to kidnapping the human brain's reward system. Withdrawal convinces an addict that the continued opioid ingestion is required to stay alive. A patient's fear of the unpleasant effects of withdrawing from opioids can drive an individual not to seek further opioid treatment. Despite a noticeably diminished quality of life to a patient

continued use of opioids is thought to be a better alternative then the deeply unpleasant effects of withdrawal.

55. After the continuous administration of opioids for an extended period of time, patients quickly grow tolerant of their analgesic effects. When that chemical tolerance increases, patients then require progressively higher doses in order to obtain at least equal levels of pain reduction he or she has grown accustomed to even including doses that are thought to be "frighteningly high." As the dosage increases, the symptoms of withdrawal increase as well. That syndrome increases a patients likelihood for becoming addicted. The FDA has already acknowledged the relationship between increased doses and the risk of further adverse effects.

56. Patients who are prescribed higher doses of opioids in conjunction with long-term opioid therapy are three to nine times more likely to become a victim of overdose than those who are prescribed low doses. It is widely suggested that maintaining a tolerance to the respiratory depression from opioid intake develops more slowly than a tolerance to analgesic effects. Therefore the practice of continuously increasing doses to abate pain can lead to overdose even when these opioids are administered as recommended.

57. Furthermore, "potential side effects from chronic use of opioids can be abuse and addiction . . . . in fact, the correct use and abuse of these agents are not polar opposites—they are complex, inter-related phenomena." It is in fact difficult to discern whether or not a patient is physically or psychologically dependent, or addicted. Withdrawal behaviors, which delineate addiction, will exacerbate when opioids are not available, when the dose prescribed is no longer effective, or when an individual withdraws from their usual dosage too quickly.

58. Widely recognized studies have demonstrated that between 30% and 40% of long-term users of opioid drugs experience problems.

59. The risks and adverse effects regarding dependence, tolerance, and addiction are fully disclosed within the labels for each of Defendants' opioids. However they were never disclosed in these many Defendants' marketing. Previous to these Defendants' deceptive marketing schemes, those risks were well-recognized by physicians and seen as a reason to prescribe opioids for the treatment of chronic pain with trepidation and as a last resort only when other treatments failed to maintain their effectiveness?

60. The duration of opioids vary. Opioids that were designed to be long lasting are prescribed to be administered once or twice daily and are alleged to provide

continuous relief generally for hours. Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian allegedly are long-acting opioids. In addition, certain opioids may be prescribed to be administered in shorter-acting formulations, which allegedly last for approximately 4-6 hours. These aforementioned short-acting opioids can be prescribed in conjunction with long-acting opioids to address "acute episodic pain." Cephalon's Actiq and Fentora are particularly fast-acting drugs that are explicitly exacted conjointly with continuous opioid therapy. These aforementioned defendants purposely promoted the idea that pain must be treated primarily with long-acting opioids on a continuous basis in conjunction with short-acting, rapid-onset opioids.

61. WHEREFORE it was previously thought that long-acting opioids were as susceptible to abuse and addiction as short-acting opioids, this view has been discredited. OxyContin's label now states, as do all labels of Schedule II long-acting opioids, that this class of drugs "expose users to the risks of addiction, abuse, and misuse, which may very well lead a patient to overdose and death." The FDA now requires that extended release and long-acting opioids adopt "Risk Evaluation Mitigation Strategies" based on the assumption that they present,

"A serious public health crisis of addiction, overdose, and death".

62. In 2013, in response to a petition to restrict the labels of long-acting opioid products, the FDA notated the "grave risks" of opioid use as, "the most well-known of which include addiction, overdose, and even death." The FDA further warned the public that "even with the proper administration of opioids under medical supervision, they can still result in life-threatening respiratory depression, coma or death?" Going forward the FDA required opioid makers of long-acting formulations to clearly exemplify these risks on their labels (defined, as noted in Section V.C.1, to include promotional materials disseminated by or on behalf of the manufacturer of the drug). In doing so, the FDA affirmed that what had previously been accepted in the treatment of pain— that the adverse outcomes from opioid use also include "addiction, unintentional overdose, and/or death" and that long-acting or extended release opioids "should be used only when alternative treatments are inefficient".

63. It must be noted that in reaching a conclusion, the FDA did not rely on new or previously unavailable scientific studies regarding the properties or effects of opioids.

64. Even though opioids are now routinely prescribed, there has never been any official substantiation pertaining to their safety and efficacy when administered on a long-term basis. These aforementioned defendants have always been acutely cognizant of gaps in knowledge pertaining to the opioids they market widely to the public. When artfully marketing these various opioid drugs to treat chronic pain, these aforementioned defendants skillfully failed to disclose the utter lack of evidence to support their use long-term and have artfully neglected to disseminate contradictory evidence that perpetual opioid therapy actually makes patients sicker then they initially were.

65. Amazingly there are no memorialized controlled studies pertaining to the use of these various opioid drugs beyond 16 weeks, and there has never been a scintilla of evidence presented for review that opioids actually improve patients' pain and function long-term? In fact the first random, placebo-controlled studies that appeared in the 1990s revealed short-term efficacy at best and only in a minority of patients. A 2004 report reviewed 213 randomized, controlled trials of treatments for cancer pain and found that even though opioids had a short-term efficacy, the data was still not sufficient enough to establish their long-term effectiveness. Subsequent reviews of opioid administration for cancer and non-cancer pain

consistently depicted a lack of data when assessing long-term outcome. In documentum, a 2007 systematic assessment of opioids for back pain concluded their limited, if any at all, efficacy for the pain they were prescribed for and that the evidence presented did not establish their efficacy regarding long-term use. Moreover, a 2011 systematic study of non-cancer pain found that the evidence to support long-term efficacy was poor at best. A year later, an additional study exemplified that there was poor evidence pertaining to long-term efficacy for morphine, tramadol, and oxycodone, and only fair evidence for transdermal fentanyl which had been approved only for use for cancer pain.

66. As a matter of fact there is clear evidence establishing that opioid drug treatments are <u>not</u> [e]ffective when treating chronic pain, and may even exacerbate patients' health. A 2006 study-of-studies established that opioid drugs as a class, failed to demonstrate any improvement in functional outcome over alternative non-addicting conventional treatments. As a matter of fact the aforementioned, "Study of Studies" stated for the record: "For functional outcomes, other analgesics were significantly more effective than were opioids." Another compilation of evidence pertaining to the administration of opioid drugs for chronic pain established that up to 22.9% of patients who participated in various

opioid trials dropped out before the study began due to the intolerable effects of opioids and that the pain relief they offered was weak over time.

67. Endo Pharmaceutical's own research studies demonstrated that patients who were prescribed opioids, as opposed to other prescription pain medicines, reported higher incidents of obesity (30% to 39%); insomnia (9% to 22%); and self-reported fair or poor health (24% to 34%).

68. Over an increased period of time opioid use has been strongly associated with an increasing prevalence of mental health issues including depression, anxiety, post-traumatic stress disorder, or substance abuse, increased psychological distress, and a greater need for health care treatments.

69. A well known pain specialist noted in an article titled, "Are We Making Pain Patients Worse," "Opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."

70. That is true both generally and for specific pain-related conditions. Studies pertaining to the use of opioids over a long-term for chronic lower back pain have been unable to establish any discernible improvement in patient function.

Conversely, research has consistently demonstrated that long-term opioid therapy in patients who have lower back injuries, has never established that patients return to work or resume physical activity after treatment with this class of drugs. This outcome is due partly to the addictive side effects as well as other mitigating factors.

71. Studies show that as many as 30% of patients who suffer from migraine headaches have been prescribed opioids as treatment. It has been well established that users of opioid drugs had the highest increase in the number of headache days per month and as a result scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation established that migraine patients who were prescribed opioids as treatment were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other traditional medications.

72. This purported lack of evidence pertaining to the efficacy of opioid long-term use has been well-documented nationally in connection with of workers' compensation claims, where some of the most detailed data exists. Claims involving workers who were prescribed opioids were almost four times more likely

to reach costs totaling more than $100,000 than those with claims without opioids, as patients who experience greater side effects are slower to return back to work. Even taking the severity of patients injuries into consideration as well as a self-reported pain score, the administration of opioid drugs for greater than seven consecutive days and further being administered more than one opioid prescription increased individual risks that the patients would be on work disability one year later. In fact the administration of opioids as a first treatment for workplace injuries actually doubled the average length of each claim.

73. Prior to the Defendants aggressive marketing campaign, it was generally accepted by the medical community that opioid drugs should be administered for short-term use only for acute pain, pain relating to surgery, and/or to abate the asperities of cancer pertaining to palliative care. In these aforementioned cases the risk of addiction plays little to no significance.

74. The World Health Organization ("WHO") published an "analgesic ladder" in 1986, outlining the treatment of cancer pain. "WHO" recommended over-the-counter or prescription acetaminophen or non-steroidal anti-inflammatory drugs ("NSAIDs") as a first line in the fight against pain, after that unscheduled or a combination of opioids, and then stronger (Schedule II or III) opioids if pain failed

to subside. The "WHO" analgesic ladder exclusively addressed the treatment of cancer pain, and never contemplated the use of narcotic opioids for chronic pain—because the use of opioids for the treatment of chronic pain was considered to be inappropriate medical practice at that time.

75. Various independent studies and articles from the 1970s and 1980s clearly exemplified many reasons to avoid opioids. Scientists had an opportunity to observe the acrimonious outcomes resulting from long-term opioid therapeutic use in pain management programs: opioids' mixed record in reducing pain long-term and failed to improve patients' function; there were greater pain complaints from patients who over time developed a tolerance to this class of drugs; opioid patients' matriculated from a cognizant state of being to a diminished ability to perform the most basic of tasks; these patients developed an inability to participate in complementary treatments such as physical therapy due to the side effects of opioids; and addiction. Notable authorities discouraged and even prohibited, the implementation of opioid treatments for chronic pain.

76. Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an

article in 1986 reported that, "Few substantial gains in employment or social function could be attributed to the institution of opioid therapy.

77. Dr. Portenoy described in 1994 the prevailing attitudes regarding the dangers of long-term use of opioids:

> "The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in

> discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction."

78. Dr. Portenoy further stated that these problems were a, "compelling reason to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."

79. In conjunction with the words of Dr. Portenoy, another researcher from the Harvard Medical School stated, "It did not enter doctors' minds that there could be a significant number of chronic pain patients who were successfully managed with opioids." The defendants collectively changed that perception.

80. The defendants' collective direct marketing was initiated in two directions and so serving two related purposes. First, the defendants implemented branded and unbranded marketing to enhance confidence amongst doctors in long-term opioid use by over exemplifying their benefits and diminishing their risks, therefore

expanding the chronic pain market exponentially. Secondly, the collective defendants employed their own sales representatives, physician spokes people who were carefully recruited, and an aggressive advertising campaign in various medical periodicals therefore emboldening their share of a broader market. The collective defendants manipulated these aforementioned activities by scrupulously designing marketing plans that implemented extensive research into prescribers habits and the efficacy of detailed sales marketing approaches and their messages.

81. Collectively the defendants conjointly but on an independent basis, engaged themselves in a widespread advertising campaign that significantly touted the benefits of their particular brand of opioid drugs. These defendants published advertisements in a wide variety of medical periodicals, ranging from those that targeted specialists, namely the "Journal of Pain" and "Clinical Journal of Pain", and in journals that were read by a wider medical audience, such as, "The Journal of the American Medical Association". The defendants' had advertising budgets that peaked in 2011, when collectively they spent in excess of $14 million on medical journal advertising alone glorifying the wider use of opioids which was nearly triple their expenditures in 2001. The advertising campaign of 2011

included, $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

82. A number of these targeted advertisements deceptively portrayed the benefits of opioid therapy for chronic pain. In 2005 Purdue Pharma, placed an advertisement for OxyContin in the "Journal of Pain" claiming that this drug was an "around-the-clock analgesic and worked continuously for an extended period of time." This particular advertisement depicted a man and a boy fishing and then proclaimed that "There Can Be Life, With Relief." This fictitious advertisement implied that OxyContin provided both effective long-term pain relief and functional improvement, claims that are factitious and completely unsubstantiated and further contradicted in medical literature.

83. Each of these collective defendants shamelessly promoted the use of opioids for chronic pain through "detailers" who are sales representatives that visit physicians and their staff in their offices as well as a small group well planned speaker programs. By establishing these close relationships with doctors were might prescribe their brand of drug, these aforementioned sales representatives scrupulously disseminated their contrived misrepresentations in a targeted, one-on-one setting that helped them to explicitly differentiate their brand of opioids and to

address individual prescribers' concerns when it came time to prescribe opioids for chronic pain. These representatives were sufficiently trained to employ techniques that helped build these personal relationships. Actavis even rolled out an "Own the Nurse" kit in order to break the ice with the doctors they were targeting.

84. These collective defendants implemented sophisticated plans to target prescribers for potential sales visits based on their specialties and prescribing habits. It was common industry practice for the defendants to purchase and then closely analyze prescription sales data from "IMS Health" which then allowed them to precisely track the rate of initial prescribing and prescription renewals by these individual doctors and then ultimately target, tailor, and observe the impact of their appeals.

85. These defendants then implemented "influence mapping," using decile rankings and similar breakdowns to identify high-volume prescribers in order to detail what would be the greatest sales impact. Endo singled out prescribers who represented 30% of its nationwide sales volume (decile Nos. 8 through 10) and planned to visit these physicians three times per month. Defendants also closely monitored doctors' prescribing after a sales representative's visit to allow them to refine their planning and messaging and to evaluate and compensate their detailers.

86. The aforementioned sales representatives over a period of time visited hundreds of thousands of doctors, including thousands to New York State prescribers where they intentionally disseminated false information regarding the risks, benefits, and ultimately the superiority of their opioid based drugs that were intended for the treatment of chronic pain. The misinformation disseminated included unsubstantiated and false claims regarding the risks of opioids for chronic pain, in particular the actual risks of addiction, withdrawal as well as, the benefits.

87. Each of these collective defendants carefully inculcated their sales force to impart pro-company messages that were specifically intended to generate prescription sales pertaining to the drugs, expressly opioids in general. That allowed these aforementioned pharmaceutical companies to precisely direct and monitor their appointed sales representatives by implementing specific action plans, training seminars, tests, scripts, role-plays, along with supervised tag-alongs, and by other means as well—to ensure that these intended individual salesman actually delivered the prescribed messages and that they did not veer off-script. These aforementioned pharmaceutical companies conjointly required their sales force to deliver aids that were first reviewed, approved, and supplied by each company and forbade these sales people from implementing what was referred to

as, "Homemade Bread," i.e., promotional materials that were not approved by the each company's marketing and compliance czar's. These many sales people adhered by mandate to the corporate training they had been given which was typically included in their work contracts. Any deviation from their company's pre-approved messaging may lead to severe consequences, including immediate termination of employment.

88. In addition to the careful training of their sales representatives, these aforementioned defendants went as far as surveying the physicians they had solicited. These surveys were closely conducted by third-party research firms who assessed how effective their core messages were to prescribers. These"verbatim" retrospectives that were specifically memorialized the disseminated messages were an essential weapon that ensured consistent message delivery to these prescribers. These appointed representatives also assisted the aforementioned defendants to gauge physicians' perceptions of, and willingness to prescribe, each defendant's opioid drugs. These memorialized corroborate findings helped to further precipitate the various types of deceptive and unfair advertising messages that each defendant disseminated nationally and in New York State.

89. Along with employing sales calls and visits, the aforementioned sales force also exemplified doctors who might be recruited as paid spokesman. The defendants' created "speakers' bureaus" in order to attend created programs with these recruited spokes doctors speakers along with extravagant meals paid for by defendants to further entice their services. The defendants and their representatives almost exclusively selected physicians who they thought of as, "Product Loyalists," while assuming that these physicians would ultimately be asked whether or not they intended to prescribe the drugs they were promoting themselves. Endo pursued specialists in the field of pain medicine which included high prescribers of the drugs they were promoting. These doctor spokes people were thought to be local thought leaders to promote the wider prescribing of Opana ER to primary care doctors. Accepting these invitations are lucrative to the spokes physician who were selected for these bureaus; honorarium pay rates ranged from $800 to $2,000 per program, all depending on the type of event they were speaking at. Even speaker training typically is compensated these spokes doctors at the rate of $500 per hour.

90. Recruiting doctors to participate in these defendants contrived speaker programs and the ancillary speaker training programs served three purposes: They

provided financial incentive to doctors to prescribe and ultimately increase their prescriptions of each particular opioid drug; it created a forum that further marketed to the speaker to their peers; and so creating an opportunity to market what they were promoting to the speaker's peers. The defendants purposely graded their speakers therefore inviting future opportunities which were based on the speakers performance, post-program sales, and product implementation. The defendants knowingly then tracked the prescribing rates of the events attendees and furthermore, Endo noted that, "Physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than they did before." After all it would make little to no sense for these defendants to keep on devoting significant resources to programs that did not increase their bottom line.

91. These many paid speaker doctors and the representatives who appointed them were always expected to stay "on message"—this was established in writing by contract which was provided to them by the defendants. Endo's exacted specific speaker rules for these paid doctor spokes people. They were mandated that "all slides must be presented in their entirety and without alterations . . . and in the sequence they were provided in." Implementing this strict set of rules was important because the FDA deems these promotional talks as part of product

labeling, and in turn requires their submission for review. Thus the doctor spokes people gave the impression that they were providing independent, unbiased presentations about the opioid drugs they were promoting, when deceptively they were presenting a scripted speech that had been previously prepared by the defendants' dedicated marketing personnel. Although these meal ingratiated speaker events are more expensive to host and typically have lower attendance than [1] CMEs, they are surreptitiously subject to less professional scrutiny so affording the defendants greater latitude in the messages they had presented.

92. These collective defendants committed massive monetary resources to help initiate sales contact with potential prescribers. During 2014, the collective defendants spent an estimated $168 million on promoting each particular brand of opioids to physicians nationwide. These funds allocated included $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis. The funds allocated for promotion was more than twice the defendants' collective spending for promotion in 2000. The appointed representatives role in defendants' overall promotional efforts was also routinely calibrated; Endo devoted 61% of it's marketing budget towards sales

representatives who reflected an "appropriate combination of personal . . . and non-personal . . . selling initiatives."

93. The reason for these aforementioned defendants allocating hundreds of millions of dollars towards promoting their own particular brands of opioids by employing their respective sales forces was because they had a keen understanding that the sales pitches they were disseminating were effective. There were a number of studies indicating that the right marketing approach can and does have a substantial impact on doctors' prescribing habits. They had also discovered that face-to-face meetings had the most effective influence on doctors intent to prescribe. The aggregate established that their sales had climbed exponentially with substantial spending. It was soon established that the level of individual prescribers, whom they targeted for these face-to-face meetings responded by prescribing more of defendants' drugs.

94. The collective defendants soon directed their efforts in order to expand opioid prescribing by exploiting a comprehensive marketing and business plan for each of the opioid drugs they were marketing. These assumptions were based on extensive market research which then prompted the implementation of ambitious plans to

lure in new prescribers and ultimately increase the tangential prescribing of more opioids.

DIRECT TARGETING OF POTENTIAL PRESCRIBERS:

95. After implementing a careful strategy the defendants began targeting particular zip codes to better solicit individual healthcare providers for increased sales. The defendants instructed their representatives to target potential providers who they thought would be more likely to prescribe by imparting more in-person access due to the likelihood these meetings would result in higher numbers of prescriptions and at higher doses. There was purposely no correlation to need or demand for opioid therapy and certainly with no thought of potential abuse.

96. Collectively the defendants' marketing plans morphed into a dual strategy, that often operated tangentially with one another. The appointed sales representatives further narrowed their marketing efforts towards pain specialists and anesthesiologists who after careful research were the highest-volume prescribers of opioids. However as a collective group they were more educated than most other practitioners about the risks and benefits of the opioids they were being solicited to prescribe. Despite those facts their goal was to increase and develop market by expanding sales regardless of risk to end users. With that in mind the defendants

became more aggressive in targeting these types of prescribers as marketing targets.

97. By expanding the market of prescribers as a group, the defendants soon discovered that they were less informed about opioids and were also more susceptible to sales marketing messages. These less educated prescribers included nurse practitioners and physician assistants who in 2012 Endo were targeted for "share acquisition" opportunities as they were "3x times more responsive than MDs to solicitations as a whole". Endo memorialized that "96% of their prescriptions were written without physician consult."

98. This newly expanded market also included internists and general practitioners who were established to be low-to mid-volume prescribers. In 2008 Activis implemented a plan to move beyond "Kadian loyalists" by enjoining their products to an "expanded audience" of "low morphine writers."

DIRECT MARKETING TO CONSUMERS:

99. These collective defendants had a keen understanding that doctors were much more likely to prescribe their particular brand of opioid medication if patients on their own volition requested their brand of drug. Endo soon discovered that greater direct communication would result in greater patient "brand loyalty," by imparting

to the public that Opana ER had longer duration and fewer discontinuations. With that knowledge strategically added to their arsenals the collective defendants took their opioid sales rhetoric directly to consumers even including patient-focused "education and support" materials. These promotional items took the form of pamphlets, videos, or other publications that patients could thoroughly ingest when visiting their physician's office. As Endo put it, "Drive demand for access through the employer audience by highlighting cost of disease and productivity loss."

100. After careful research the defendants discovered that one of the largest obstacles to patients being enticed into starting and then remaining on their particular brand of opioid medication that included switching from a competitor's brand of drug—was out-of-pocket cost? They soon established a strategy to overcome the obstacle by providing these potential patients with financial assistance to cover their insurance co-payments. This was done through vouchers and coupons that were being distributed during face-to-face meetings with potential prescribers. Actavis highlighted their own brand of co-pay assistance in 2008 that was good for up to $600 per patient per year, as a surefire method to help incite conversions to Kadian from their competitors brand of drugs like Avinza and MS Contin. Janssen joined the fray by distributing 1.5 million savings cards worth

$25 each. The petitioner was enticed by Purdue Pharma when they offered him through an advertising campaign, a discount card that reimbursed him for up to seventy-five dollars in co-payments per prescription renewal.

IMPARTING THEIR BRAND TO CONSUMERS OVER OTHERS:

101. OxyContin manufactured by Purdue had become the clear market leader in prescription opioid therapy, with 30% of the market for analgesic drugs in 2012. By 2010 the defendants were facing increased resistance from the medical community and regulators due to accruing problems from opioid addiction and abuse. These market conditions incentivized the defendants to embark on different market strategies with a particular emphasis on their own branded product being less a subject to diversion, abuse, and addiction with the inducement of possibly grabbing more market share from Purdue and some other competitors.

102. Endo initiated a concerted effort to entice their prescribers into "switching" from OxyContin to Opana ER, and Actavis and Janssen seeing their success did the same for switches to Kadian and Nucynta ER. Now there was pressure to stand out amongst these other drugs which resulted in the collective defendants exemplifying marketing schemes that then began reflecting in deceptive and harmful messages to

physicians and consumers. Janssen initiated a plan that emphasized "value" messaging in support of Nucynta ER in 2008 that included invalid claims of less dose escalation, lower toxicity, fewer withdrawal symptoms, and less dependence. In 2009 Opana ER invested in market research that honed in on greater potency with lower abuse potential compared to OxyContin.

BEYOND THE OFFICE VISIT:

102. The defendants reached out to additional prescribers by expanding beyond prior traditional sales calls and those often relied upon speaking events to new avenues to disseminate their messages. These new tactics included soliciting prescribers via voice mail, postcards, and email which came to be known as, "e-detailing." The defendants additionally created new platforms for their speakers by advancing "peer to peer" programs such as teleconferences and webinars that were able to reach prescribers nationally. These programs allowed the defendants to move their marketing to hard-to-reach audiences, prescribers at hospitals, academic centers, and other locations that formally limited or prohibited face-to-face solicitations. Enacting these new methods enabled each defendant to heavily promote their own brand of drugs through new avenues of communication.

103. Implementing these new marketing avenues with consistency nationwide was done through national and regional sales training of their appointed representatives; national training of local medical liaisons, company employees responding to physician inquiries; centralized speaker training; single designated sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. These aforementioned sales representatives and physician speakers were required to stick with prescribed talking points, sales messages, and slide desks, and supervisors rode along with them periodically to both check on their performance and compliance.

103. As implemented nationwide, the defendants extensively tracked the prescribing habits of New York State health care providers using the data they collected to further target their potential recruiting efforts. The top echelons of prescribers were were closely targeted by city, region, zip code, and sometimes by facility levels, with an ample amount of information depicting their specialty, prescribing patterns (including product and dose), product loyalty and refill history. Providers' prescribing higher volumes were ranked and sorted into specific target groups.

104. This new information enabled the defendants to target each sales territory in order to single out prescribers who could have the biggest sales impact. Indeed, one New York City pain specialist who estimated that he wrote 600-700 opioid prescriptions each month for patients who suffered the asperities of long-term chronic pain, watched as the defendants representatives saw him regularly because it meant "big money for these people." Tracking the prescribing behavior of doctors also enabled the defendants to hone in on trends; Actavis routinely identified prescribers on a monthly basis who had the greatest increases and decreases in prescriptions being written.

105. The data the defendants collected, included a number of verbatim messages that further detailed activity (including electronic, meeting, and event promotional activity) and then proffered them to a panel of their choosing consisting of office-based physicians, hospital-based physicians, nurse practitioners, and physician assistants throughout various districts in the United States. On a monthly basis the panelists reported via online surveys then commenting about the promotional activity in which they participated that month. The responses were based on the perception of the main message of the promotion. The responses received by the research company were reported word-for-word as "verbatim's."

106. Health care providers repeatedly stated that the defendants' representatives made a concerted effort to market their brand of drugs as safe, with low risk of addiction or lower risk than competing opioids, and claimed that their company's product was the drug of choice for chronic pain conditions such as low back pain and osteoarthritis. The defendants' representatives also repeatedly claimed by implication that their brand of drugs had minimal or low abuse potential; were safer than other pain medications; and, in the case of Cephalon's Actiq and Fentora, were appropriate for off-label use.

107. These collective defendants employed unbranded, third-party marketing, which they engaged for their national marketing strategies to further promote their brand of opioid drug. The third party representatives disseminated the defendants strategies through a vast network of third-party [2] KOLs and Front Groups, who acted in concert by funding, assisting, encouraging, and directing their efforts. Simultaneously the defendants exercised critical control over the content of the messages being disseminated by these third parties, and by distributing certain

Footnote [2]: Key Opinion Leaders are physicians who influence their peers' medical practice, including but not limited to prescribing behavior.

effective materials themselves. These unbranded marketing representatives created the illusion of independence and credibility that was unwarranted effective as a strategy. The unbranded marketing campaign allowed the defendants to evade oversight from federal regulators which in turn gave them greater freedom to expand their deceptive messages.

108. Drug companies that market and distribute opioid drugs are subject rules that require them to pursue truthful marketing standards. The collective defendants were mandated to adhere to the law by: (a) being consistent with labeling that must be supported by substantiated scientific evidence; (b) labeling my not include false or misleading statements or omissions of substantiated fact; and (c) there may be no obfuscation regarding the drug's benefits and risks. [The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.] [21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6)]

109. Furthermore, the Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the sale through interstate commerce of drugs that are "misbranded." A drug is

"misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular; [Adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended; Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material. "The term "accompanying" is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like —disseminated by or on behalf of the manufacturer of the drug.Thus, Defendants' promotional materials are part of their drugs' labels and required to be accurate, balanced, and not misleading.]

110. Labeling is deemed to be misleading when it is not based on substantiated evidence, if it materially misrepresents the benefits of the drug, or if it omits or obfuscates material information about the frequency or severity of a product's risks. "The most serious risks set forth in a product's labeling are generally material to any presentation of efficacy." The FDA notes that, "because people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are

included." Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive.

111. It is also [i]llegal for pharmaceutical companies to disseminate materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly cannot be supported by the results of the study." Drug companies are further barred from disseminating comparisons between their branded drugs and other manufacturers drugs that represent or imply that "one drug is safer or more effective than another drug in some particular when in fact it has not been demonstrated to be safer or more effective by means of substantiated evidence or substantiated clinical studies.

112. Although the FDA must approve a drug's label, it is the drug company's responsibility to establish beyond doubt that the material contained within its label is accurate and complete and has been updated to reflect any new relevant information. All promotional materials disseminated must be first submitted to the FDA as they are first implemented. However the FDA is not required to pre-approve these materials in advance; if however, after review, the FDA establishes that these materials are misleading, they can issue a untitled warning letter. The FDA proffers untitled letters for violations for overstating the effectiveness of a

drug or employing claims that lack context or balanced information. These warning letters when issued address promotions imply safety or health risks and usually indicate the FDA may take further enforcement action forthwith. [21 C.F.R. § 113. The defendants marketed their opioids both directly and indirectly by employing third parties to validate (such as scientists, physicians, or patient or professional organizations) and in order to appear independent to further create the illusion of credibility. The FDA however has made clear that its promotional requirements apply to both forms of marketing:

> FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf.....x

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99.101(a)(4), 21 C.F.R. § 202.1(e)(6)(ii). See 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); see also Wyeth v. Levine, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 C.F.R. § 314.70(c)(6) (iii)(A-C) (allowing manufacturers to make changes that "strengthen . . . a warning, precaution, or adverse reaction" or "strengthen a statement about drug abuse, dependence, psychological effect, or overdosage").]

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> Therefore, a firm is responsible for the content generated by its employees or any agents acting on behalf of the firm who promote the firm's product. For example, if an employee or agent of a firm, such as a medical science liaison or paid speaker (e.g., a key opinion leader) acting on the firm's behalf, comments on a third- party site about the firm's product, the firm is responsible for the content its employee or agent provides. A firm is also responsible for the content on a blogger's site if the blogger is acting on behalf of the firm.

114. In addition to being implemented directly or through third parties, drug companies' promotional activities may be branded or unbranded; unbranded does not refer to a specific drug? It more generally applies to a state of disease or a treatment thereof. By implementing unbranded communications, the defendants found a way to sidestep the FDA's extensive regulatory framework that governs branded communications.

.....[FDA, Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics, January 2014, at 1, 4, http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/ guidances/ucm381352.pdf.]
.....

115. These collective defendants disseminated many false, misleading, imbalanced, and unsupported statements that were proffered indirectly, through [2] KOLs and Front Groups, and through unbranded marketing devices. These [2] KOLs and Front Groups were an important factor in the development of the defendants' marketing plans in order to give the appearance of being independent which left them outside of FDA oversight. [3] These unbranded materials were a vehicle to disseminate information and instructions that generally concern opioids generally and were contrary at best or inconsistent with the information and instructions that had been listed on the defendants' particular branded marketing materials and drug labels. Sadly this was done with the collective defendants' knowledge of the risks, benefits pertaining to opioids. The defendants implemented this strategy knowing that unbranded materials typically not submitted or reviewed by the FDA.

116. As unbranded messages were being proffered through third-party avenues, the defendants adopted, cited, edited and approved these messages in their name, then distributing these messages knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. Brochures and other materials that were "disseminated by the defendants, on their behalf, were in violation of constituted drug "labeling" standards that are prohibited from being false or misleading in any

particular way. See 21. C.F.R. 202.1(e)(7)(l)(2). The defendants' sales representatives made it a habit to distribute third-party marketing publications that were deceptive to their target audiences. It is of de facto importance to know that the defendants are responsible for the dissemination of those materials.

117. The defendants actively guided, reviewed, and approved many of the false statements issued by these third parties, ensuring that the defendants remain aware of the context. The defendants maintained control over these spurious messages and by funding, directing, editing, and distributing these materials, they acted conjointly with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

118. There was no evidence to establish that using opioid drugs was effective for the treatment of chronic pain. The FDA put the defendants on notice, and would not allow such claims to be continued in these third party branded materials. Instead of adhering to the FDA's request to, cease and desist, they instead

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FOOTNOTE [3]: This regulation provides: "Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and the references published . . . containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling, as defined in section 201(m) of the act." As labeling, such third party-created content distributed by a drug company may not be misleading and must meet the accuracy, substantiation, and fair balance requirements in the FDCA.

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continued to perpetrate the same unsupported claims, that the opioid drugs they were distributing would help patients to sleep, return to work, or walk more easily, as these unbranded marketing materials previously stated.

119. The promotional materials being proffered by the defendants abetted the creation and distribution excluding warnings and instructions that were mandated by the FDA who required that drug labels that accurately addressed the risks and benefits that the defendants were well aware of. These third party materials either failed to disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied that potential patients faced any serious risk of addiction.

120. By surreptitiously acting in concert with these third parties, the defendants both avoided the FDA scrutinizing what they were doing and promulgating a false appearance that the messages being proffered were the views of independent third parties. In order to further obfuscate what defendants were prophesying, they claimed their messages were being "independently" corroborated. Claiming "Independent" corroboration gave the message they were disseminating greater credibility as their products were being distributed more broadly and doctors were not "pushing back" when they received these reinforcing promotional materials from a non-profit organization such as the, American Pain Foundation ("APF")

which they displayed in their offices for their patients absorb. Nonetheless, these independent promotional materials were machinations when in reality the defendants maintained close contact with their partnered third parties, as they paid for and were well cognizant of the misleading information they were disseminating to the public depicting the use of opioids for the treatment of chronic pain, then regularly altering their misleading, pro-opioid messages.

CLAIM FOR RELIEF

121. Violation of N.Y. Gen. Bus. Law § 349 (McKinney)(a) Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful. (b) [W]henever the attorney general shall believe from evidence satisfactory to him that any person, firm, corporation or association or agent or employee thereof has engaged in or is about to engage in any of the acts or practices stated to be unlawful he may bring an action in the name and on behalf of the people of the state of New York to enjoin such unlawful acts or practices and to obtain restitution of any moneys or property obtained directly or indirectly by any such unlawful acts or practices. In such action preliminary relief may be granted under article sixty-three of the civil practice law and rules.

122. Violation of N.Y. Gen. Bus. Law § 350 (McKinney) False advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful.

123. Violation of 15 U.S.C.A. § 1125 (West) **(1)** Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which--**(A)** is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or **(B)** in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

124. Violation of 21 U.S.C.A. § 352 (West) [A] drug or device shall be deemed to be misbranded--(a) False or misleading label **(1)** If it's labeling is false or misleading in any particular. Health care economic information provided to a

payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement, shall not be considered to be false or misleading under this paragraph if the health care economic information relates to an indication approved under section 355 of this title or under section 262(a) of Title 42 for such drug, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 355 of this title or under section 262 of Title 42. The requirements set forth in section 355(a) of this title or in subsections (a) and (k) of section 262 of Title 42 shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request.

124. Violation of 21 U.S.C.A. § 331 (West), The following acts and the causing thereof are prohibited: **(a)** The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is

adulterated or misbranded. **(b)** The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce. **(c)** The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. **(d)** The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb-3 of this title. **(g)** The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded. **(h)** The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title, which guaranty or undertaking is false. **(k)** The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce

and results in such article being adulterated or misbranded. **(n)** The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 374 of this title. **(w)** The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 381(d)(3) of this title; the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 381(e) or 382 of this title, or with section 262(h) of Title 42; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

125. The petitioner, Jay Brodsky reserves the right file further claims upon discovery of facts.

PRAYER FOR RELIEF

126. Compensatory: ONE MILLION DOLLARS 00/100

127. Punitive: as the court finds appropriate

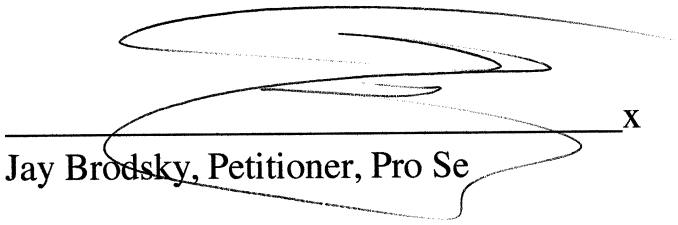
128. Negligent Infliction of Emotion Distress: ONE MILLION DOLLARS 00/100

129. Intentional Infliction of Emotional Distress: ONE MILLION DOLLARS 00/100

130. Collecting Damages: as the court finds appropriate

WHEREFORE, the petitioner, Jay Brodsky thanks the esteemed court for its consideration of this pending matter before it.

Signed this 4th day of May, 2018 at Great Neck, New York



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Jay Brodsky, Petitioner, Pro Se